

K960338
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SECTION 19: SUMMARY OF SAFETY AND EFFECTIVENESS

APR 23 1996

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

19.1 SUBMITTER INFORMATION

- a. Company Name: Elekta Instrument AB
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- e. Date Summary Prepared: January 19, 1996

19.2. DEVICE IDENTIFICATION

- a. Trade/Proprietary Name: Stereotactic Body Frame
- b. Classification Name: Radiographic Head Holder

19.3 IDENTIFICATION OF PREDICATE DEVICE

<u>Company</u>	<u>Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
Radionics	Gill-thomas-cosman (Gtc) Relocatable Head Holder S	K934523	2/8/95
Med-Tec	Vac-lok Immobilization System	K935300	7/18/94

19.4 DEVICE DESCRIPTION

The Stereotactic Body Frame utilizes a reference system which is external to the patient's body. Using this stereotactic system, the coordinates of a target can be reproducibly localized during diagnostic examination and treatment. The Frame has built-in copper or copper sulfate solution reference indicators for CT or MR determination of target coordinates. These reference indicators, which produce fiducials on the CT or MR images, permit x, y and z coordinate determination for localization of the target. A diaphragm control attached to the Frame can be used to minimize respiratory movements. Horizontal positioning of the Frame, in the scanner or on the treatment couch, is achieved using an adjustable base on the Frame.

Marker devices are used for reproducible positioning, after fixation of the patient in a vacuum pillow. An arc-ruler is attached to the Frame and a chest marker device on the arc-ruler is used for alignment of the patient. This is based on two skin marks over the patient's sternum. Longitudinal alignment is controlled by skin marks over the tibia using a frame-mounted laser. The coordinates used for patient positioning can be easily read on the arc-ruler holding the sternum marker and on the longitudinal ruler, along which the arc-ruler can be moved.

19.5 SUBSTANTIAL EQUIVALENCE

The Elekta Stereotactic Body Frame is substantially equivalent to other stereotactic frames currently in commercial distribution by Radionics and immobilization systems in distribution by Med-Tec in terms of the intended use of achieving a safe and accurate fixation and refixation of a patients body part for localization of targets for radiotherapy treatment with Linear accelerators.

The fundamental technical characteristics are similar to those of the predicate devices and are listed on the comparison chart provided in this 510(k) submission. Differences that exist between these systems relate to physical

appearance and materials which do not affect the relative safety or effectiveness of the device.

19.6 INTENDED USE

The Stereotactic Body Frame is a device designed for stereotactic diagnostic localization and stereotactic radiotherapy of extracranial targets.

19.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the predicate and legally marketed devices is provided in the following table.

19.8 PERFORMANCE DATA

A study was conducted to evaluate the strength and deformation of the Stereotactic Body Frame under normal use, the influence of radiation on the behavior of Frame material which has been subjected to repeated use and the radiation attenuation when irradiating different parts of the Frame was assessed. The results of this study demonstrated that the Stereotactic Body Frame is capable of safely and accurately repositioning the patient in relation to an external reference system.

19.9 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.